Remarks

Amendment to the claims

Claims 1-19 are pending. Claims 1-19 are amended to further limit the dry powder to the one that contains microparticles formed of the drug defined therein and a polymer or diketopiperazine. Support for the amendment to the claims is found at p. 3, lines 5-8.

An important aspect of the claims is the ability of the drug particles to be delivered to and remain in the nasal region, which requires the particles to have a size in the range of between 10 and 20 microns. If the particles have a size below 10 microns, the particles will pass through the nasal region and go into the pulmonary system; if the particles have a size above 20 microns, the particles will not be delivered to the nasal region.

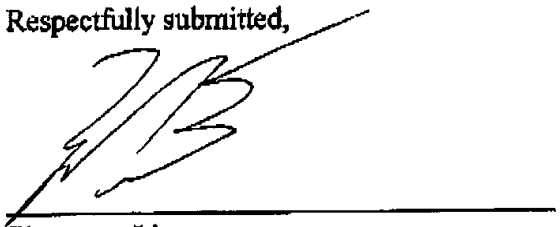
In relevant part, U.S. Patent No. 5,164,194 to Hettche ("Hettche") discloses a dry powder formulation that contains from 0.0005% to 2% azelastine. The particle size for the dry powder should not be greater than 20 microns. The azelastine is **mixed with** inert carrier substances or **drawn up onto** inert carrier substances. Hettche does not disclose or teach forming micrparticles of the drug with a polymer or a diketopiperazine by dispersing the drug in the polymer or diketopiperazine. Nor does Hettche disclose or teach encapsulating the drug with a material. Therefore, the claims as amended, define a dry powder which is clearly distinguishable from Hettche.

Further, the amended claims are non-obvious over U.S. Patent No. 5, 352,461 to Feldstein et al. ("Feldstein"), which describes a diketopiperazine drug delivery system in the form of microspheres encapsulating bioactive agents for topical, local or systemic parenteral or enteral administration. In particular, Feldstein teaches particles of between 0.1 to 10 microns (col. 3, lines 21-23), which, to one of ordinary skill in the art, would pass through the nasal

region to the pulmonary system (see, Edwards et al., "Recent advances in pulmonary drug delivery using large, porous inhaled particles" in J. Appl. Physiol. 85(2):379-85 (1998) (Review)). Feldstein, as such, does not provide an enabling disclosure of the present composition and method of using and making thereof defined in the claims, which require the particles to have a size between 10 to 20 microns. Moreover, because the particles used in Feldstein would pass through the nasal region while the particles defined in the claims of the present claims would retain in the nasal region, Feldstein **teaches away** from the claimed composition and the method of making and using thereof as defined in any of claims 1-19. Therefore, claims 1-19 are non-obvious over Feldstein, alone or in combination with Hettche

Allowance of claims 1-19 is therefore earnestly solicited.

Respectfully submitted,



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PRELIMINARY AMENDMENT

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the enclosed and all documents shown as being attached is being facsimile transmitted to the U. S. Patent and Trademark Office on the date shown below.

Date: January 22, 2003

Peggy D. Bailey

APPENDIX I: Marked-up Copy of Claims as Pending

1. (amended) A composition for the nasal administration of a drug [to a patient comprising

a drug]in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for administration to the nasal region,

the dry powder form comprising microparticles formed of the drug and a polymer or diketopiperazine.

2. The composition of claim 1 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

3. The composition of claim 2 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

4. The composition of claim 1 wherein the drug is formulated in a polymeric carrier.

5. The composition of claim 1 wherein the drug is formulated in a diketopiperazine formulation.

6. The composition of claim 1 wherein the dry powder formulation consists essentially of drug.

7. (amended) A drug delivery device for nasal administration comprising

a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation for administration to the nasal region, and

a device for delivering a measured dose of the drug to the nasal mucosa,

wherein the dry powder form comprises microparticles formed of the drug and a polymer or diketopiperazine.

8. The device of claim 7 wherein the device is a nasal insufflator.

9. The device of claim 7 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

10. The device of claim 7 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

11. The device of claim 7 wherein the drug is formulated in a polymeric carrier.

12. The device of claim 7 wherein the drug is formulated in a diketopiperazine formulation.

13. The device of claim 7 wherein the dry powder formulation consists essentially of drug.

14. (amended) A method of administering a drug to the nasal region of a patient in need thereof, comprising nasally administering a dry powder form of a drug having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for nasal administration,

wherein the dry powder form comprises microparticles formed of the drug and a polymer or diketopiperazine.

15. The method of claim 14 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

16. The method of claim 14 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

17. The method of claim 14 wherein the drug is formulated in a polymeric carrier.

18. The method of claim 14 wherein the drug is formulated in a diketopiperazine formulation.

19. The method of claim 14 wherein the dry powder formulation consists essentially of drug.